

Application No.: 10/823,456
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Remarks/Arguments:

Remarks

Claims 1-16, 21; 24-41; 44-57; 59-64; and 79-91 are currently pending. The Examiner has rejected claims 1-21, 24-41, 44-57, 59-64, 79, 80, 82, 83, 85, 86, 88, 89, and 91. Through this Amendment, claims 8 and 17 have been canceled, and claims 1, 32, 47, 48, 49 and 79 have been amended. Specifically, claims 1, 32 and 49 have been amended to recite that the woven portions of the first tubular end, the second tubular end and the bulbous woven section are seamlessly transitioned and claims 1, 32, 49, and 79 have been amended to recite that the ends of the implantable graft have continuous warp yarns common to each end. Support for this amendment may be found, for example, at page 1, paragraph 1, and page 3, paragraph 6 of the application as filed. The Examiner has withdrawn claims 81, 84, 87, and 90 from consideration, asserting that there is no generic or linking claim.

The Examiner has objected to claims 47 and 48 under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 47 and 48 have been amended to depend from independent claim 32. Thus, the Applicant asserts that this objection has been overcome.

The Examiner has objected to claim 8, alleging double patenting in view of claim 7. In view thereof, the Applicants have canceled claim 8.

The Examiner has rejected claims 1-21, 24-41, 44-48, and 79-91 under 35 U.S.C. § 112 for failing to distinctly claim the subject matter which the applicant regards as the invention. In particular, the Examiner has asserted that independent claims 1, 32 and 79 recite "said yarns", which was insufficient to provide antecedent basis. Through this Amendment, the Applicant has amended independent claims 1, 32, and 79 to recite "fill yarns". Thus, the Applicant asserts that this rejection has been overcome.

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Section 103 Rejections

The Examiner rejected claims 1-8, 10, 12, 14-16, 18-21, 24-29, 31-36, 38-41, 44-56, 59-64, 79, 82, 85, 88, and 91 under 35 U.S.C. §103(a) as allegedly being unpatentable over Nunez et al. (5,800,514) in view of Yachia et al. (2004/0093065). The Examiner acknowledged that "Nunez does not explicitly state the middle section is bulbous or that a third section has a diameter the same as the first section." The Examiner relied upon Fig. 6 of Yachia, alleging that Fig. 6, reference numeral 610, depicted a bulbous portion. For the reasons set forth below, this combination is impermissible and the claims submitted herewith are patentable over these references, taken individually or in combination. Reconsideration and withdrawal of the references is respectfully requested.

Applicant has amended the claims of the present application to recite that the woven portions of the first tubular end, the second tubular end, and the bulbous woven section are seamlessly transitioned and that the ends of the implantable graft have continuous warp yarns which are common throughout. Neither Nunez nor Yachia, taken individually or together, teach or suggest the combination of woven portions of the first tubular end, the second tubular end, and the bulbous woven section are seamlessly transitioned with continuous, common warp yarns from one end of the implantable graft to the other. Specifically, Nunez teaches a seamless woven portion that gradually changes or tapers in diameter. The Examiner admitted that Nunez does not teach a bulbous portion. Thus, neither can Nunez teach the seamless transition from the first and second tubular ends to the bulbous portion, as disclosed in amended independent claims 1, 32, 49, and 79.

The Examiner relied on FIG. 6 of Yachia, alleging that the Yachia teaches a graft or a stent-graft that has a bulbous section, with two flanking ends 615a and 615b. The paragraph [0038] which the Examiner refers to, states that the lining 610 is integral with two stents 615a and 615b. It is clear from the teachings of Yachia that by the term "integral" is meant that two stent portions are fitted onto the ends of a central lining portion to create a composite device. This is distinctly different than the present invention, which creates its central bulbous portion using yarns common to both ends of the graft, and which by both first increasing and then decreasing the number of common warp yarns, seamlessly create the bulbous shape. Yachia does not disclose three seamlessly woven portions, the central portion being bulbous, where each of the sections are seamlessly transitioned. Rather, Yachia teaches that two stents

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may flank a lining, as shown in FIG. 6 and discussed in paragraph 38. Yachia's FIG. 6 and the disclosure of Yachia do not disclose or suggest that the central lining or stents may be woven, methods of weaving a bulbous central portion, that there is a seamless transition between the two end stents and the central lining portion, or that the central lining portion is bulbous. Moreover, Yachia does not disclose warp yarns at all, or that the ends of the device have continuous warp yarns which are common throughout. In stark contrast, Applicants FIG. 1 references the seamless portions 13, 15, between the three portions, clearly showing their seamless nature, and this language is clearly recited in the claims.

In establishing a *prima facie* case of obviousness, the cited reference must be considered for the entirety of its teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* It is only through hindsight reconstruction and selective picking and choosing does the Examiner attempt to reach the present invention through the bare recitation of a shape depicted in FIG. 6 of Yachia. It is well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993). Such hindsight reconstruction by the Examiner is clear as the Examiner has read into the reference the undisclosed, untaught, and unsuggested element by merely concluding it "obvious". Thus, the Examiner impermissibly modifies Yachia and summarily alleges that Yachia teaches a bulbous section (610) in order to make it read on the present invention.

In view of the *KSR* decision, the USPTO published new obviousness guidelines for examiners on October 7, 2007. (See, Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* 57526 Federal Register, Vol. 72, No. 195, October 10, 2007.) The PTO guidelines require "clear articulation of the reason(s) why the claimed invention would have been obvious" quoting relevant sections from the *KSR* decision. Applicant respectfully asserts that the Examiner's combination of references does not teach the elements and features of the invention and that the Examiner has provided insufficient reasoning in his alleged rejection determination. Thus, the presently amended independent claims, and the claims which depend therefrom, are non-obvious, and are likewise patentable.

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Moreover, the Supreme Court addressed the standard for obviousness in its decision of *KSR International Co. v. Teleflex Inc., et al.*, 550 U.S. ____; 127 S.Ct. 1727; 167 L.Ed.2d 705; 82 U.S.P.Q.2d 1385 (2007). In order for an examiner to establish a *prima facie* case of obviousness after *KSR*, some degree of predictability is necessary. For example, the following statements from *KSR* show the importance of predictability:

The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. (82 U.S.P.Q.2d 1395).

If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. (82 U.S.P.Q.2d 1396).

A court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. (82 U.S.P.Q.2d 1396).

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. (82 U.S.P.Q.2d 1397).

In view of the *KSR* decision, the USPTO published new obviousness guidelines for examiners on October 7, 2007. (See, Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* 57526 Federal Register, Vol. 72., No. 195, October 10, 2007.) The PTO guidelines require "clear articulation of the reason(s) why the claimed invention would have been obvious" by quoting the following from the *KSR* decision:

[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. (*Id.* at 57528, column 3, to 57529, column 1).

The USPTO then identified seven different "rationales" to reject claims for obviousness based on *KSR*, i.e., rationales A-G. In each, the word "predictable" or the phrase "reasonable expectation of success" appears in the heading, the text underneath the heading, or both. For example:

- A. "Combining Prior Art Elements to Known Methods to Yield Predictable Results." (*Id.* at 57529, column 1).
- B. "Simple Substitution of One Known Element for Another to Obtain Predictable Results." (*Id.* at 57530, column 1).
- C. Use of Known Technique to Improve Similar Devices (Methods, or Product) in the Same Way

One of ordinary skill in the art would have been capable of applying this known method of enhancement to a 'base' device (method, or product) in the prior art and the results would have been predictable. (*Id.* at 57530, column 3).

D. "Applying a Known Technique to a Known Device (Method, or Product) Ready for Improvement to Yield Predictable Results" (*Id.* at 57531, column 1).

E. "Obvious to Try" – Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success" (*Id.* at 57532, column 1).

F. Known Work in One Field of Endeavor May Prompt Variations of it for Use in Either the Same Field or a Different One Based on Design Incentives or Other Market Forces if The Variations Would Have Been Predictable to One of Ordinary Skill in the Art"

The rationale to support a conclusion that the claimed invention would have been obvious is that design incentives or other market forces could have prompted one of ordinary skill in the art to vary the prior art in a predictable manner to result in the claimed invention. (*Id.* at 57533, column 1).

G. Some Teaching, Suggestion, or Motivation in the Prior Art That Would Have Led One of Ordinary Skill to Modify the Prior Art Reference or To Combine Prior Art Reference Teachings To Arrive at the Claimed Invention

(2) a finding that there was reasonable expectation of success". (*Id.* at 57534, column 1).

Accordingly, a proper rejection of a claim based on obviousness requires the examiner to explain how the prior art leads a person skilled in the art reasonably to predict or expect that the claimed invention will be successful.

Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd., 83 USPQ2d 1169 (Federal Circuit 2007) is a post *KSR* decision in which the Federal Circuit articulated standards for establishing non-obviousness. Again, predictability of success is required.

Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation. (*Id.* at 1176).

...the court found that there was no reasonable expectation in the art that changing the positions of a substituent on a pyridyl ring would result in beneficial changes. (*Id.* at 1177).

...we disagree with Alphapharm that that statement provided a reasonable expectation to one of ordinary skill in the art that performing the specific steps of replacing the methyl group of the 6-methyl compound with an ethyl group, and moving that substituent to the 5-position of the ring, would have provided a broad safety margin ... (*Id.* at 1178-1179).

Further, Section 2143.02 (II) of the MPEP states that "Obviousness does not require absolute predictability; however, at least some degree of predictability is required."

In the present application, Applicants recite that Nunez teaches a method of seamless weaving, but Nunez has the specific problem of not teaching more complex shaped grafts, in which applying Nunez "may not result in a seamless graft which anatomically matches complex lumen contours". See, paragraph [0027] of the present Application. Neither does Yachia teach or suggest how to seamlessly weave a graft or stent which anatomically matches a complex lumen. Not only does Yachia not discuss weaving or seamless transitions, as previously discussed, the integral sections shown in FIG. 6 are fitted together as a composite. This teaching is contrary to and quite divergent from Nunez and its seamless diameter transition. Thus, one looking to improve upon Nunez would neither look to or learn anything of import from Yachia which would help in seamless transitions. Moreover, not only is there no motivation to combine these references, but if one were to do so, they would not arrive at the claimed invention. This is because at best, Yachia's general teachings relate to a non-woven shape as shown in FIG. 6 for stents. This shape teaches nothing relevant with respect to seamless transitions. Also, Nunez discloses transitions which either increase or decrease in diameter, but not both in one transition region. Thus, Yachia fails to remedy the deficiencies of Nunez. Given the arguments above, it is not understood why these references can be properly combinable.

The references, taken individually and in combination, do not disclose, teach, or suggest the present invention as set forth in the presently amended independent claims 1, 32, 49, and 79. Further, the reference cited by the Examiner taken individually and together, do not suggest a reasonable expectation of success or predictable results in their combination. The Examiner admits that Nunez is deficient and relies, incorrectly, on Yachia. For the reasons set forth above, Yachia does nothing to cure the deficiencies of Nunez. Therefore, Applicants respectfully submit that independent claims 1, 32, 49 and

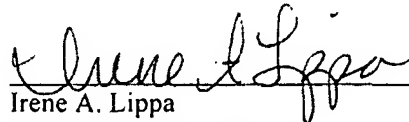
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79, and all claims dependent therefrom, are patentably distinct from the references cited, taken individually and in combination. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



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